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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/534,034 | 05/06/2005 | Ratan Chaudhuri | MERCK-3004 | 9740 |
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| EXAMINER | | | | ARNOLD, ERNST V |
| ART UNIT | | | | PAPER NUMBER |
| | | | | 1616 |

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/534,034 | CHAUDHURI ET AL. |
| | Examiner | Art Unit |
| | Ernst V. Arnold | 1616 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-10 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-10 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>05/06/05</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The Examiner acknowledges receipt of application number 10/534,034 filed on 05/06/2005 and is a 371 of PCT/EP03/11846 filed on 10/24/2003, which claims benefit of 60/424,316 filed on 11/07/2002 and is a CIP of 10/616,494 filed on 07/10/2003.

Claims 1-10 are pending in the application.

Applicant is advised to remove the period after 1,000 in claim 1.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

Foreign language submissions will only be considered to the extent an English language abstract or translation has been provided to the Examiner.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2 and 5-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Ghosal U.S. Patent No. 6,124,268.

Claim 1 is drawn to a anhydrous composition comprising (a) an antioxidant comprising over 40% by weight of hydrolysable tannins having a molecular weight of less than 1,000; (b) a substantially anhydrous or non-aqueous liquid vehicle functioning to disperse the antioxidant. (By substantially anhydrous applicant means that the final formulation contains preferably less than 1% by weight water (Page 5, lines 15-16)).

Ghosal discloses an antioxidant composition derived from the fruit of the *Emblica officinalis* plant (Column 2, lines 20-32). In one disclosure, a liposomal gel formulation comprised of 0.5% CAPROS-lecithin (1:1) complex prepared by mixing 1mM CAPROS with a lecithin in peroxide free ether or toluene (Column 4, lines 52-54 and column 5 lines, 58-67). The composition of CAPROS is: Emblicanin-A and Emblicanin-B (35-55%); Punigluconin (4-15%); Pedunculagin (10-20%); Rutin (5-15%); and gallo-ellagitannoids (10-30%) (Column 2, lines 37-44) and is the only antioxidant disclosed for this formulation thus comprising over 40% by weight of antioxidants in the composition. Lecithin sequesters the antioxidant and is dispersed in a volatile, substantially anhydrous organic solvent (peroxide free ether or toluene) thus meeting the limitations of claim 1. Lecithin is an organic ester thus meeting the limitation of instant claim 5.

Ghosal discloses a composition (Phase A-1) comprised of propylene glycol isoceteth-3 acetate (glycols are a structural agent defined by applicant on pages 5 and 6 of the instant specification); octyl methoxycinnamate (a known sunscreen agent); benzophenone-3; homomenthyl salicylate; steareth-2; acrylates/C10-30 alkyl acrylate

crosspolymer; synthetic wax (waxes can be used as a structural agent as defined by applicant on page 7 of the instant specification); dimethicone (a silicone elastomer that can be used as a gelling agent as defined by applicant on page 8 of the instant specification); and CAPROS (Column 8, lines 46-65; Example 11 Phase A-1). The mixture of these components (column 9, line 16) meets the limitations of instant claims 1, 2, 5, 6, 7 and 8. Ghosal discloses combining, stirring and heating to 80° C the components of Phase A-1 (Column 9, line 16).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ghosal (U.S. Patent No. 6,362,167) and Vatter et al. (U.S. Patent No. 6,475,500).

Applicant claims: An anhydrous composition comprising
(a) an antioxidant comprising over 40% by weight of hydrolysable tannins having a molecular-weight of less than 1,000;
(b) a substantially anhydrous or non-aqueous liquid vehicle functioning to disperse the antioxidant.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Ghosal discloses an extract blend used in a method of blocking free radical processes that comprises by weight 35-55% of Emblicanin-A and Emblicanin B; about 4-15% of Punigluconin; and about 10-30% of Pedunculagin; about 0-15% of Rutin and about 10-30% of tannoids of gallic/ellagic acid (Claims 1-3). The Examiner considers instantly claimed preferred amount of Rutin (less than 0.01%) within the range 0 to 15% Rutin specified by Ghosal.

Vatter et al. teach an anhydrous cosmetic composition that improves skin color, texture and feel which is prepared by mixing: DC9040 cross linked elastomer gel (a dimethicone gelling agent); cyclomethicone (a silicone oil); silica, titanium dioxide (a sunscreen agent), iron oxide (Ronosphere LDP); isoeicosane (permethyl 102A); alkyl methicone (DC AMS C30 wax) (a structural agent); iron oxides-silicone coated; and titanium dioxide-silicone coated (Column 30, lines 47-64 and Column 32, lines 5-6). Vatter et al. teach that bismuth oxychloride is a suitable agent to add to the composition (Column 13, lines 9-10). Vatter et al. teach that polyethylene glycol is a suitable humectant to add to the composition (Column 11, lines 60-61). Vatter et al. teach that antioxidants can be incorporated into the compositions of their disclosure (Column 23, lines 55-67)

Ascertainment of the difference between the prior art and the claims
(MPEP 2141.02)

Ghosal does not expressly teach a composition comprising the antioxidant extract blend and a substantially anhydrous or non-aqueous liquid vehicle further comprising a sunscreening agent or bismuth oxychloride.

The features recited in applicant's claim 3 are noted. The difference between claim 3 and Ghosal is that Ghosal does not expressly disclose 20-35 wt% Emblicanin A and 10-20 wt% Emblicanin B. Ghosal discloses a combined amount of 35-55 wt% of the two ingredients, which is sufficient to encompass the combined amounts of said ingredients in applicant's claim 3. Additionally, at for example, 40 wt% total of the two ingredients, as disclosed and suggested by Ghosal, equal amounts of the two ingredients would be 20 wt% each. Hence, given the variability of extract content, which would be expected by the ordinary skilled artisan in this field, the percentages of Emblicanin A and B as set forth in claim 3 would have been fairly suggested from Ghosal's teachings.

The maximum absorbance feature recited in applicant's claim 4 is noted. Nowhere else in applicant's disclosure is this feature explained any further. However, applicant does state: "present invention is applicable to all types of extracts of *Phyllanthus emblica*" (specification page 1, lines 13-14). Applicant also states that the cited reference by Ghosal does in fact disclose extracts of *Phyllanthus emblica* (specification page 1, lines 11-14). Therefore, given that Ghosal's extract contains the same exact antioxidants as required by applicant's claim 1, the analytical characteristics

set forth in applicant's claim 4 (dependent on claim 1) are presumed to be characteristics that must necessarily be present in Ghosal's extract and its antioxidants, particularly in view of applicant's statement that Ghosal's extract is suitable and further in view of absence of any other evidence regarding the maximum absorbance disclosure. The U.S. Patent Office is not equipped with analytical instruments to test prior art compositions for the infinite number of ways that a subsequent applicant may present previously unmeasured characteristics. When as here, the prior art appears to contain the exact same ingredients and applicant's own disclosure supports the suitability of the prior art composition as the inventive composition component, the burden is properly shifted to applicant to show otherwise.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add a sunscreen or bismuth oxychloride, as suggested by Vatter, to the composition of Ghosal and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Ghosal suggests that the formulation can be used for personal care compositions for skin care in the form of solutions, lotions, creams or gels but does not provide guidance on the proper excipients to use in the skin care compositions (Column 7, lines 30-34). Vatter et al. provide guidance on excipients to use in anhydrous cosmetic products, which include antioxidants, sunscreen agents and bismuth oxychloride as discussed

above. One of ordinary skill in the art would have sought guidance from Vatter et al. to make anhydrous skin care compositions from the anhydrous composition of Ghosal and produce the instant invention.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claim Rejections - 35 USC § 103

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over (U.S. Patent No. 6,649,150 (filing date 04/11/2002)) in view of Vatter et al. (U.S. Patent No. 6,475,500).

Applicant claims: An anhydrous composition comprising
(a) an antioxidant comprising over 40% by weight of hydrolysable tannins having a molecular-weight of less than 1,000;
(b) a substantially anhydrous or non-aqueous liquid vehicle functioning to disperse the antioxidant.

Determination of the scope and content of the prior art (MPEP 2141.01)

U.S. Patent No. 6,649,150 (hereafter referred to as the 150' patent) discloses a powder composition consisting essentially of by weight: 20-35% Emblicanin A, 10-20%

Emblicanin B, 15-30% Pedunculagin and 3-12% Punigluconin 0.001 to 0.01% by weight of Rutin, less than about 1% flavonoids, said weight percentages having an average deviation of not more than 10% (Claim 1; column 13, lines 37-42) and characterized by an optical density of 0.8 at wavelength 410 nm, 0.1 at wavelength 470 nm, 0.08 at wavelength 530 nm, 0.09 at wavelength 590 nm and 0.02 at wavelength 650 nm (Claims 11-15; column 14, lines 4-20). The 150' patent further discloses a formulation according to claim 1 and a cosmetically or pharmaceutically acceptable carrier (Claims 5 and 17, column 13, lines 48-50 and column 14, lines 23-25). The powder of the composition consists of essentially over 40% by weight of Emblicanin A, Emblicanin B, Pedunculagin and Punigluconin and less than about 1% by weight of flavonoids (Claim 18; column 14, lines 26-29) and the powder according to claim 18 can consist essentially of by weight 50-80% of Emblicanin A, Emblicanin B, Pedunculagin and Punigluconin and less than about 0.06% by weight of flavonoids (Claim 19; column 14, lines 30-33). In addition, the formulation can further comprise a photoprotective agent (sunscreen) (Claim 8; column 13, lines 57-59).

Vatter et al. is relied upon as described above.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

The 150' patent does not expressly disclose an anhydrous composition comprising an antioxidant comprising over 40% by weight of hydrolysable tannins comprising Emblicanin A, Emblicanin B, Pedunculagin and Punigluconin and a

substantially anhydrous or non-aqueous liquid vehicle functioning to disperse the antioxidant or expressly disclose the addition of bismuth oxychloride.

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made modify the antioxidant composition of the 150' patent by mixing it in a non-aqueous substantially anhydrous liquid vehicle with bismuth oxychloride as taught by Vatter et al. to produce the instantly claimed invention.

One of ordinary skill in the art would have been motivated to do so because the 150' patent suggests that the composition can be formulated with a cosmetically or pharmaceutically acceptable carrier (Claims 5 and 17). One of ordinary skill in the art would have found the disclosure of Vatter et al., which suggests the use of antioxidants and bismuth oxychloride in the anhydrous cosmetic composition and produced the instant invention.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Double Patenting

Claims 1-3, and 5-9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 6, 8-35 of copending Application No. 10/616,494. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter of the instant invention embraces or is embraced by the subject matter of the copending application. Instant claims 1-3 drawn to an anhydrous composition comprising antioxidants and a substantially anhydrous or non-aqueous liquid vehicle are embraced by copending claims 1-4 and 6. Instant claim 5 drawn to a substantially anhydrous or non-aqueous liquid embraces copending claims 8-10. Instant claim 6 drawn to a structural agent embraces copending claims 11-13. Instant claim 7 drawn to a gelling agent embraces copending claims 14-17. Instant claim 8 drawn to a sunscreen agent embraces copending claims 18-24. Instant claim 9 drawn to bismuth oxychloride embraces copending claims 25-34. Instant claim 10 drawn to a method of producing an anhydrous composition embraces copending claim 35.

One of ordinary skill in the art would have recognized the obvious variation of the instant application over the copending application. The adjustment of particular working conditions (e.g., selection of a bismuth oxychloride having a particle size of less than 35 microns (80% within range) and a median size of 8.0 to 20 microns) is deemed merely a matter of judicious selection and routine optimization of standard working conditions, which is within the ability of one of ordinary skill in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ernst Arnold
Patent Examiner
Technology Center 1600
Art Unit 1616
May 02, 2006

A handwritten signature in black ink, appearing to read "Johann Richter". The signature is written in a cursive style with a small oval flourish around the beginning of the name.

Johann Richter, Ph.D. Esq.
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